

PATENT
09/042,460
Docket 019/224

REMARKS

This paper is responsive to the Office Action dated February 13, 2003 (Paper No. 47).

Claims 5, 9, 20-28, and 31-34 are pending in the application. Claims 5 and 9 are withdrawn. Claims 35-43 are newly added by way of this amendment, and fall within the elected group. Accordingly, claims 20-28 and 31-43 are under examination.

The amendments do not add new matter to the disclosure. Motifs T, A, B, C recited in Claims 20 and 22 are supported by Figure 5 of the application as filed; Motifs 1, 2, and D are supported by Figure 4. The size of 50 to 150 kDa (Claim 31) is supported on page 6, lines 1-3. The hybridization conditions of Claim 39 are supported in the section on page 91, line 11 to page 92, line 10. The other claim amendments are supported throughout the disclosure and claims as previously presented.

Claims 21, 22, 24, 25, and 27 are allowed. The other claims previously examined stand variously rejected.

Reconsideration and allowance of the application is respectfully requested.

Interview

The undersigned wishes to express his gratitude to Examiners Sumesh Kaushal and Jeffrey Fredman for the courteous and constructive interview conducted at the Patent Office on November 14, 2003; and by telephone on January 6, 2004. Amendments and remarks presented in this response were discussed during the interviews.

Declaration

The Office Action indicates that the Declaration previously filed in support of this application pursuant to 37 CFR § 1.67(a) is defective because it claims priority to applications to which applicants have since cancelled their priority claim.

Procedures are underway to obtain an executed replacement Declaration from the inventors. It will be filed with the Office in due course.

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Claim Objections

Claims 32-34 are objected to for failing to recite a specific SEQ. ID NO for each motif. The motifs have now been moved to claims 20 and 22.

It is respectfully submitted that no SEQ. ID NO is required for any of the motifs now presented in the claims. The motifs listed in claims 20 and 22 are chemical structures that comprise less than four specified amino acids in consecutive sequence. Accordingly, no sequence identifier is required according to 37 CFR § 1.821. Applicants wish to save the burden of generating a new sequence listing, and having the Office enter a new sequence listing into the file. The motifs have been fully searched and considered during examination of this application.

Withdrawal of this rejection is respectfully requested.

Rejections under 35 USC § 112 ¶ 1:

Claims 20, 23, 26, and 31-34 stand rejected under 35 USC § 112 ¶ 1 on the basis that the specification is not enabled for the making of polynucleotides that encode TERT having at least 90% sequence identity to SEQ. ID NO:2, and having telomerase catalytic activity. The Office Action indicates that this deficiency will be cured by requiring that the TERT protein contains telomerase amino acid motifs.

Applicants gratefully acknowledge the Examiner's thorough consideration of this issue, and the careful crafting of the arguments presented in the last Office Action.

Nevertheless, applicants respectfully disagree, for reasons indicated previously. The response filed on June 13, 2003, enclosed a Declaration under 37 CFR § 1.132 by Gregg B. Morin, Ph.D. Dr. Morin provided the following points in support of the ease to which telomerase variants within the claimed scope can be generated.

- TERT sequences in different eukaryotes can have identities of less than 30%, and yet they perform essentially the same function. Telomerase components appear to be interchangeable between mammalian cells. Yet mouse TERT is only about 64% identical to human TERT at the amino acid level. Thus, considerable variation in the sequence can be accommodated without losing function.
- Motif sequences in DNA polymerase enzymes are known to be highly tolerant to mutations in amino acid sequence. About 42 of the 63 residues in the motif sequences have been changed in the course of evolution of just seven eukaryote TERT proteins. Experimental mutation studies are expected to show even more plasticity.

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- It would be easy to construct a library of thousands of TERT variants based on the prototype mouse TERT sequence, using any one of several techniques known in the art at the time this application was filed. The library could then be easily screened using assays described in the specification to identify variants with telomerase activity.

Accordingly, functional telomerase variants could be generated from the prototype mTERT sequence (SEQ. ID NO:1), and tested in a high throughput manner. The number of possible variants is not a consideration, since any desired number of functional variants can be generated without undue experimentation, based on the prototype sequences provided in the disclosure, in combination with standard mutation and screening methods known in the art at the time the application was filed. Some of the variants obtained in this fashion will have variations in one or more of the motifs.

Dr. Morin's § 1.132 Declaration was refuted in the last Office Action only by Examiner's argument. In the absence of an Examiner's Affidavit or other documented factual basis for refuting the specific points made in Dr. Morin's Declaration, this is insufficient to maintain an enablement rejection under § 112 ¶ 1.

Nevertheless, applicants' commercial interest in this invention aligns with embodiments that contain at least one of the motifs indicated in claims 20 and 22 as amended. Accordingly, reference to the motifs has now been incorporated into the base claims. Applicants will pursue additional coverage to this and other embodiments of the invention in subsequent related applications.

Withdrawal of this rejection is respectfully requested.

Claim 28 stands rejected under 35 USC § 112 ¶ 1 as not being enabled by the specification. The Office Action indicates that the invention falls within the realm of gene therapy, which it considers a highly experimental area of research.

Applicants respectfully disagree for reasons previously indicated. Nevertheless, claim 28 has been amended to refer to an isolated cell. Accordingly, claim 28 does not read on whole living animals in which an mTERT gene has been mutated by recombinant means.

Withdrawal of this rejection is respectfully requested. The skilled reader will recognize that polynucleotides and cells used in making mTERT knockout mice still come within the coverage of the claims under examination in this application.

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Request for Examiner's Affidavit

Still pending before the Office is the Request for an Examiner's Affidavit, filed in this application on October 1, 2003, pursuant to 37 CFR § 1.104(d)(2).

Contingent upon allowance of the application, the Request is hereby cancelled.

Request for a further Interview

Applicants respectfully request that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines there are other matters to be addressed, applicants hereby request an interview by telephone.

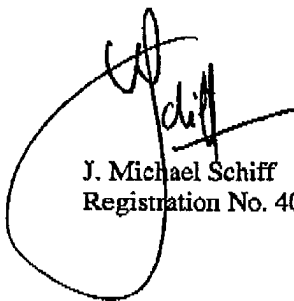
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Fees due

Accompanying this Amendment is a Fee Calculation Sheet authorizing the Commissioner to charge the Deposit Account for the additional independent and dependent claims.

No other fee is believed payable for consideration of this paper and the accompanying documents. Nevertheless, should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicants hereby petition for such relief, and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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